Questionable Practices in the Laboratory

Joseph Solsky
US Army Corps of Engineers
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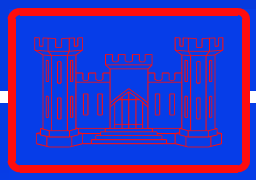
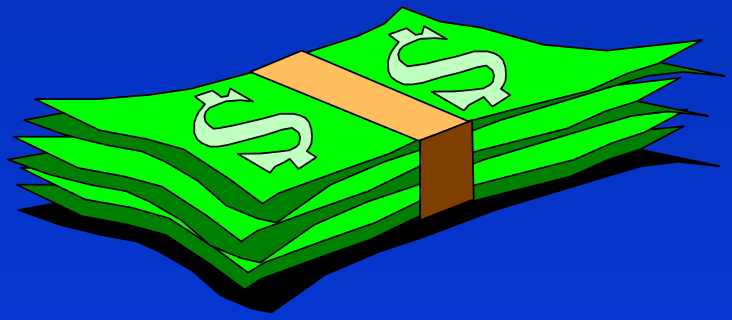
Past "Questionable Practices"

- Practices observed include: Dry labbing; Peak shaving; Peak enhancing; Time traveling.
- These practices involved the deliberate direct manipulation and/or alteration of data.
- No basis for performing these practices other than to meet specific contractual requirements and avoid financial penalties.



Penalties for These Practices



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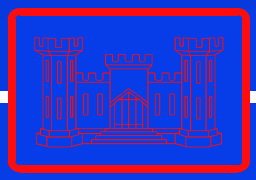
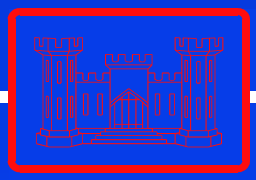
The World in Transition

- Prescriptive versus performance based methods.
- Pressure on the lab - employ knowledgeable experts to properly implement these methods. Market over capacity causing bidding war and corner cutting.
- Pressure on the regulator - properly define what PBMS is and how its quality is to be defined.
- Pressure on the buyer - properly define the DQOs to get the data needed at a fair cost.



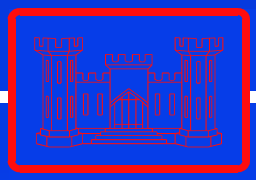
Questionable Practices

- Establishing initial calibration curves.
- Evaluation of CCV solutions.
- Reporting narrow LCS recovery ranges.
- Reporting wide MS recovery ranges.
- Determination of MDLs.



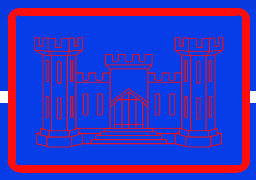
Questionable Practices

- Inconsistent tuning practices
- Misidentification of GC/MS peaks
- Missed retention time windows for CCVs
- Evaluation of Laboratory SOPs/QAPs
- Repeating QC Samples
- Special Treatment for QC Samples



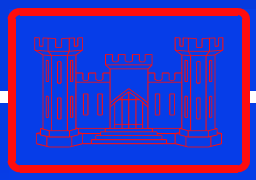
Are These Practices Fraudulent?

- I will NOT attempt to directly answer this question.
- Some previous “Questionable Practices” resulted in criminal/civil convictions.
- Black’s Law Dictionary defines fraud to include: a knowing misrepresentation of the truth, or intentional concealment of a material fact - through a statement or conduct or entry - to induce another to act to his or her detriment.



Establishing Init Cal Curves

- The running of six or more standards for methods that state ‘a minimum of five points’ and then selectively discarding points to meet QC criteria.
- Upper and lower point(s) can be discarded based upon detector response with appropriate adjustments made to linear range or reporting limits.



Evaluation of CCV Solutions

- The averaging of the % Difference across all target analytes even when one or more target analytes show significant variations.

Reporting Narrow LCS Ranges

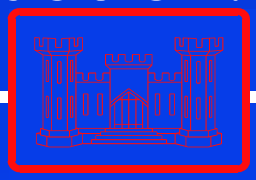
- The reporting of narrow LCS recovery ranges when laboratory generated control charts show significantly wider ranges.
- If the ranges are too wide, then methods should be modified to achieve the desired performance.
- LCSs should be spiked with the target analytes of concern, at the levels of concern, in the matrix of concern.

Reporting Wide MS Ranges

- The reporting of wide MS recovery ranges when laboratory generated control charts show significantly narrower ranges.
- MSs should be spiked at the same levels with the same target analytes as the LCS.

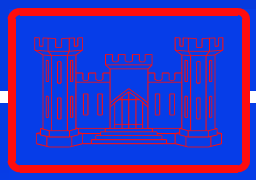
Determination of MDLs

- The running of eight or more standards and then selectively discarding points to achieve a lower MDL.
- The issue of the ‘not detected’ target analyte has caused great confusion (detection limits vs quantitation limits vs reporting limits).
- The use of an ‘MDL Check Sample’ could help clarify this situation.



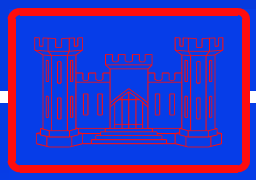
Inconsistent Tuning Practices

- The picking of the single scan or average of a series of scans that meet the desired criteria.
- A consistent approach must be used when performing tunes.



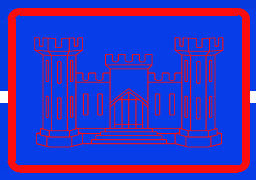
Misidentification of Peaks

- Calibration curves are being generated from the wrong target analyte.
- Second source standards should be used to verify the primary source standards.
- Instrument raw data should be reviewed to verify the correct identification of all peaks in calibration standards and that all peaks look ‘appropriate’.



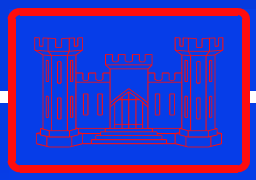
Missed Retention Time Windows

- Laboratories are performing unnecessary manual integrations to find peaks that have missed these windows.
- When windows are missed, this should be a clear signal to the analyst that corrective action is necessary.
- Missed retention time windows can result in the reporting of false negative data.



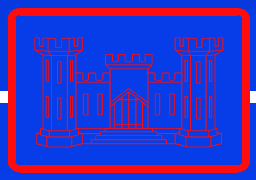
Evaluation of Lab SOPs/QAPs

- SOPs/QAPs that do not accurately reflect what the laboratory actually does.
- Documents that contain misleading statements or errors.
- The incorporation of these lab documents into project specific plans creates problems when these errors are present.



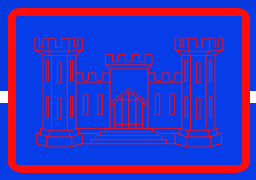
Repeating QC Samples

- Labs have been observed running certain QC samples multiple times until one passes.
- QC samples can be repeated once to verify that the problem is real.
- When QC samples fail twice, this should be a clear signal to the analyst that corrective action is necessary.



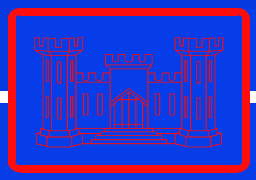
Special Treatment for QC Samples

- Labs have been observed treating QC samples differently than regular samples.
- The same procedures used to measure QC samples should be used for the regular samples.
- Sufficient time should be allowed for each analysis to avoid interactions between analyses.

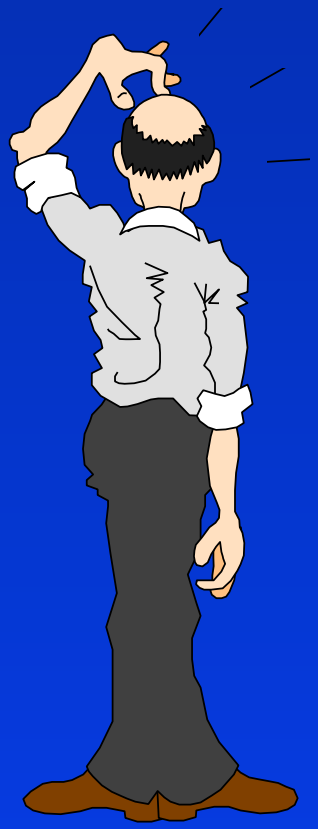


Demonstration of EnviroQuant GC/MS Software

- The two main software packages in current use are Enviroquant by Agilent Technologies and Target by Thru-Put.
- This software is very powerful and does a good job - but data must still be reviewed.
- What is manual integration and why is it necessary?
- Applying the correct initial calibration strategy.



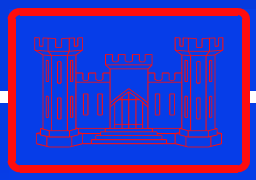
Why Is This Happening?



- Cost factors.
- Level of Expertise factors.
- Unethical Behavior
- Other Factors.

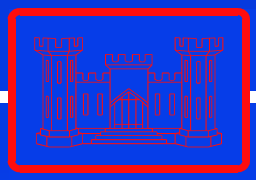
Cost Factors

- The price paid is often not sufficient to cover the costs of producing the product.
- The labs should not bid this way.
- The client should not accept low bids without considering the quality factor (‘best value’ procurement strategy).
- This is a free market economy - ‘Let the buyer beware’ or ‘You get what you pay for’.



Level of Expertise Factors

- Some laboratories have let their most experienced staff go.
- Lack of understanding regarding the fundamentals of analytical chemistry at both the laboratory and data user levels.
- Thinking that the computer will always give you the correct answer.



Why Unethical Behavior Occurs

- Real or perceived pressures
- Lack of ethics education and awareness
- Lack of management oversite and review
- Lack of knowledge or confidence in appropriate ways to solve problems
- Lack of fortitude and personal standards

Rationalization for Cheating

- I'll lose my job if I don't
- We'll lose client business
- Everyone else does it
- It's not really significant
- It's just one time

Other Factors

- The ‘CLP’ mentality - prescriptive!
- Data validation issues.
- The writers of the methods must work together with the users of the methods to minimize misunderstandings.
- Good communication is essential.

Conclusion

- We are swamped.
- These are serious issues.
- Should we trust the lab community more?
- Need to manage our data more efficiently.